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Report Highlights:

Most of the norms and regulations relevant to food and agricultural imports to Romania were harmonized with the EU ones. Currently, the process of transposing the *acquis* into domestic legislation is being accelerated, as the authorities are determined to move faster towards country's European accession, scheduled, optimistically, for 2007.

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Table of Contents

I. FOOD LAWS	4
The Ministry of Agriculture, Forests, Waters and Environment	4
The Veterinary and Food Safety Agency (VFSA)	5
The Ministry of Health	5
The National Authority for Consumer Protection (NACP)	6
II. LABELING REQUIREMENTS	6
Specific requirements for selected product labeling	7
III. PACKING AND CONTAINER REQUIREMENTS	8
1. Details on the merchandise origin and destination	8
2. Means of transport	9
3. Specific Requirements for Poultry Meat	9
IV. FOOD ADDITIVES REGULATIONS	10
V. PESTICIDE AND OTHER CONTAMINANTS	10
VI. OTHER REGULATIONS AND REQUIREMENTS	10
Proper export documentation	10
VII. OTHER SPECIFIC STANDARDS	12
Organic Food	12
Products derived from Biotechnology	13
Legal Framework for Biotech in Romania	13
Contact Information	14
Monitoring and Enforcement	14
Traceability	14
Notification Dossier	15
Phytosanitary regulations	15
Veterinary regulations	16
Marine Products	16
VIII. COPYRIGHT/ TRADEMARK LAWS	18
Patents	18
Copyrights	18
IX. IMPORT PROCEDURES	18
APPENDIX. GOVERNMENTAL REGULATORY AGENCY CONTACTS	20

DISCLAIMER: This report has been prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bucharest, Romania for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies were not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Please contact this office, if you have any comments, corrections or suggestions about the material contained in this report. Our telephone, fax, and e-mail address are provided at the end of this report.

I. FOOD LAWS

Several Government agencies and ministries in Romania have responsibilities related to agri-food supply safety and quality and regulate food importation. Most of the relevant norms and regulations were harmonized with the EU ones. Currently, the process of transposing EU laws into domestic legislation is being accelerated, as the authorities are determined to move faster towards country's European accession, scheduled, optimistically, for 2007.

Licenses, permits, health and quality certificates are required in order to produce, process or import agri-food products. Even though the legislation is in place, its enforcement is not always effective.

The most relevant provisions are set out within the following general framework:

- Government Emergency Ordinance No. 97/2001 regarding food production, distribution and commercialization.
- Law 214 of April 19, 2002, effective from May 2002, enforces and amends GOR Ordinance 49/2000 on obtaining, testing, utilization, and commercialization of genetically modified organisms (GMOs), as well as products derived from GMOs.
- Law 67/1997 on wine and wine-making practices, modified as per GOR Ordinance 34/2000.
- Ministerial Order 86/1998 providing the list of geographical indications and traditional names admitted for wine labeling in Romania.
- Ministerial Order 17/2000 providing norms for distilled spirit commercialization, referring to origin, production, bottling, labeling, and quality.
- Ministerial Order 38/2001 with provisions for distilled spirits commercialization.
- Government Decision 760/2001 providing technical norms for natural mineral water exploitation and commercialization.

These pieces of legislation are jointly proposed and/or endorsed by the GOR agencies with competency in protecting consumers and lay down conditions and requirements regarding food quality all along the marketing chain.

The Ministry of Agriculture, Forests, Waters and Environment

As of today, the Ministry of Agriculture, Forests, Waters and Environment (MAFWE) is the specialized body of the central public administration being under governmental jurisdiction. It applies the Government's strategy in the field of agriculture, food processing, rural development, as well as forests, waters and environment field.

However, pursuant to an already announced Government reshuffle, the Ministry of Environment will be set up independently in the first half of 2004.

MAFWE has attributes related to:

- a. agricultural and food policy design and implementation, in cooperation with product-specific inter-professional organizations;
- b. initiating and promoting legislation which regulates food production, distribution, importation;
- c. authorizing the activity of food processing companies; supervising law observance by firms which produce, process and sell agri-food products;
- d. elaborating standards for agri-food products in conformity with Codex Alimentarius, compliant with FAO and WTO documents.

Within the MAFWE, the *General Directorate for Policy Design and Implementation* regulates both crop production (including approvals for new seed varieties and biotech products and phytosanitary activity) and livestock production.

Likewise, the *General Directorate for Environmental Protection* has competency in environmental risk assessment (including for GMOs), monitoring activities that might harm human health and the environment.

Under the Ministry of Agriculture, Waters, Forests and Environment the following agencies and institutes participate in the regulation of the agri-food market:

- The Testing and Control Lab for Seeding Material Quality.
- The State Institute for Vegetable Breed Testing and Registration.
- The National Office for Wines.
- The National Agency for Livestock Breed Amelioration and Reproduction.

Further information on the main activities of the Ministry of Agriculture, Waters, Forests and Environment can be found at: <http://www.maap.ro>

The Veterinary and Food Safety Agency (VFSA)

In January 2004, a new executive body was established (via the GOR Ordinance 90/2003 and the GOR Emergency Ordinance 42/2004), by reorganizing the sanitary-veterinary and food processing departments, previously components of the MAFWE.

Currently, the Agency performs activities related to animal health and foodstuffs of animal origin hygiene and safety. Its activity will be significantly broadened to all aspects generally encompassed by food safety regulating and monitoring.

The Agency organizes and coordinates all sanitary-veterinary activities, elaborates national norms and regulations, including on the use of animal medical drugs. It also has attributes in animal reproduction and breed improvement. It is responsible for negotiating health certificates with international veterinary authorities for animals and products of animal origin for Romanian imports, in order to ensure conformity with the national veterinary requirements. It issues health certificates for live animals/livestock products exported from Romania. The Agency is responsible for monitoring and controlling the animal health condition nation-wide.

According to its constitutive act (GOR Ordinance 90/2003), the Agency assesses risks possibly associated with food and feed consumption. To make sure that consumers have access to product information, VFSA will post information on the Agency's Web site, consistent with applicable disclosure laws.

Other ministries and Governmental bodies involved in the regulation of the agri-food market are:

The Ministry of Health

The Ministry of Health is responsible for overseeing the production and registration of drugs, food additives, and medical equipments. It is also responsible for the public health as it relates to food and contaminants.

Thus, prior to begin operations, food processing Romanian firms and multinational companies established in Romania must obtain the approval of the Ministry of Health, which has competency in authorizing and controlling the activity of the companies involved in food production, processing and distribution.

The Public Health General Directorate and the State Sanitary Inspection within the Ministry of Health are responsible for food safety and public health. Law no. 438/2002 refers to food additives used in products for human consumption. A list of forbidden additives is further provided in this report.

The official web site of the Romanian Ministry of Health is: www.ms.ro

The National Authority for Consumer Protection (NACP)

The National Authority for Consumer Protection is a Government agency established with the aim of protecting the consumers' rights and interests. Its activity is performed within the framework given by the GOR Decision 166/2001 and the GOR Decision 349/2001.

NACP is actively involved in proposing, endorsing and promoting legislation related to consumer protection, including for ensuring food safety, and is responsible for harmonizing it with the relevant EU norms and regulations. Specifically, NACP has competency in regulating food product processing, packaging, labeling, preservation, storage, transportation, importation and distribution.

It conducts lab analyses and tests in its own or other accredited facilities for assessing food quality and possible risks and widely distributes the agency's conclusions via public awareness campaigns.

It enforces law observance through surveillance and monitoring at all links of the marketing chain. Law violations may become infringements according to the penal law and NACP has the right to charge fines and/or request the other authorities to temporary or indefinitely suspend the activity of the operators that do not observe the legal provisions.

More information about the National Authority for Consumer Protection can be found at the following web site: www.apc-romania.ro

II. LABELING REQUIREMENTS

The following authorities are responsible for regulating and enforcing labeling requirements in Romania:

- The Ministry of Agriculture Forests, Waters and Environment
- The Ministry of Public Health
- The National Authority for Consumer Protection
- The Veterinary and Food Safety Agency

The methodology and requirements for food labeling for are set out in the GOR Decision 106/February 2002 - further detailed in its accompanying Methodological Norm 7/2002 .

Beginning with February 2002 all packaged/canned food products for retail distribution are required to have Romanian language labels.

Bilingual labels (English/Romanian) are required on all products exported to Romania.

The labels must contain the following compulsory specifications:

- the name of the product;
- the ingredient* list (for processed products only). These ingredients must correspond to the ones specified in the technical description of the product. The ingredients must be presented in descending order as a percentage of the total weight of the product. The vitamins and minerals must be also mentioned in the list;
- the net content (weight/capacity);
- the expiration date (best before);
- the required storage conditions (temperature, humidity, etc.), when applicable;
- usage instructions, in case the absence might result in improper usage;
- place of origin or provenance if its absence would mislead consumers;
- information meant to help the lot identification, which has to correspond with the number written in the export documents.
- the name and address of the producer/packager/ distributor/ importer
- date of manufacturing.

*Ingredients must be specified if they belong to the following categories: colorants, preservatives, antioxidants, emulsifiers, gels, stabilizers, aroma (flavorings), acidity correctors, modified potato starch, sweeteners antifoam, melting salt.

In addition to these specifications, the labeling of alcoholic beverages requires the alcohol concentration to be displayed, in percent terms at 20 degrees Celsius, if it is greater than 1.2%. These requirements do not apply to the products classified under the HTS code 22.04 and 22.05 of the Romanian import schedule.

It is forbidden to use label specifications that refer to potential effects on human health, such as: energizer, fortifier, tonic or refresher.

Specific requirements for selected product labeling

1. Dairy products:

- labeling must specify the fat content, in percent terms;
- for the pasteurized milk the following specification is required: "Store at temperatures of 2-4 degree C";
- the processing technology (pasteurized/UHT sterilized);
- the dry matter content for powdered milk;
- nutritional data for dietetic and dairy food products (energetic value, proteins, glucose, fats, fatty acids, fiber and sodium) as well as the added flavorings.

2. Meat and products derived from meat. The label must specify:

- the animal specie the meat comes from;
- the processing technology/treatment used (salted, smoked, boiled, refrigerated, frozen, sterilized);
- for meat products, the type of casing (natural or collagenic membrane, edible or non-edible).

3. Eggs and egg products

When shelving the product a label should be attached mentioning:

- fresh big eggs (weight > 50 grams/egg) or
- fresh small eggs (weight between 40-50 grams/egg).
- the expiration date should be stamped on each piece of egg.

4. Vegetables and fruits: the date of freezing, if applicable.

5. Natural juices: the minimum fruit content (in percent terms); if obtained from concentrate, this will be specified on the label, as well as whether the juice is with or without fruit pulp.
6. Genetically modified products: According to Law 214/2002 (“the Biotech Law”), the producer is responsible for labeling biotech products placed on the market. This complies with EU legislation and regulations 1/39/98, 49/2000, and 50/2000. When applying for a biotech product deregulated status, the applicant is required to provide a description of the envisaged conditions for placing the product on the market, including use, handling, and a proposal for labeling and packaging which should comply with the requirements laid down by Law 214/2002. The label shall clearly state if the genetically modified organism is present. The label bearing the inscription “This product contains genetically modified organisms” is compulsory. There is currently no law or regulation governing the use of labels such as biotech-free, non-biotech, GMO-free, or non-GMO, Law 214/2002 states that within a period of 10 years procedures for such labeling will be established. The GOR Decision 106/February 2002 - further detailed in its accompanying Methodological Norm 7/2002 - provides more on the labeling methodology of foods obtained from biotechnology or containing genetically modified additives derived from GMOs. Interestingly, this norm is narrowed to foodstuffs delivered as such to the final consumer and to processed food entirely or partially obtained from: (i) genetically modified soybean and/or (ii) genetically modified corn. “Product derived from GM Soybean” or “product derived from GM corn” must be clearly written on the label. These additional labeling requirements can be ignored if the content of biotech soybean or corn is less than 1 percent in total ingredients.

III. PACKING AND CONTAINER REQUIREMENTS

Packing and container requirements in Romania do not differ from general international standards. The packaged products must specify on their labels the following information:

1. Details on the merchandise origin and destination

- the country of origin;
- the country from where the product is dispatched;
- the consignor;
- the consignee;
- the country of destination.

The required information may be written directly on the packages or on “stick-on” labels. Romanian authorities will accept the information written only on separate documents that accompany the products in two situations:

- a. The prepackaged products will change their form before they reach the final consumer and they will not be sold for HRI consumption.
- b. The products are destined to HRI consumption, but only after processing.

In the case of prepackaged frozen products, the labels will mention that “re-freezing after defrosting is prohibited”.

The Romanian authorities will not accept any inconsistency between the number of establishment (producer) or the shelf life written in the export documents and the ones written on the labels.

All U.S. exporters are advised to ask the importer about special requirements regarding labeling of goods they intend to export.

Romanian authorities do not accept the transfer of the labels from one establishment to another even if such establishments belong to the same producer and are officially inspected by the FSIS authorities.

All the information written on the certificates and the labels must be comprehensible and clear, with no traces of change.

All animal product shipments must be accompanied by the export certificate, health certificate and quality certificate/conformity declaration.

2. Means of transport

- for air transportation: the flight number;
- for transportation on water: the name of vessel and the no. of the container.

Also, the seal number should be posted on the container.

The packaging practices must comply with the EU regulations, with which the Romanian relevant legislation was harmonized. This refers to the packaging materials, the presence of stamps and/or of the requested specifications.

Container shipments specified as dangerous require special permission.

3. Specific Requirements for Poultry Meat

In September 2002, the Romanian Ministry of Agriculture and the Ministry of Health jointly issued a regulation on the requirements for packaging poultry meat, which was effective from November 23, 2002.

This regulation impacts bulk- packed products. According to it, bulk packed products are still be accepted by Customs, and can be sold in wholesale, retail and to restaurants and institutions. Bulk packed products for retail and wholesale must however be repacked in packages of unspecified size. Since the US were in 2003 the top poultry meat exporter to Romania, it is important to note that:

- a. Bulk packed products (i.e. the U.S. industry's 4x10) can be imported and sold to institutions, restaurants, and processors, wholesalers and retailers.
- b. Poultry cuts removed from bulk packages at wholesale and retail outlets must be repackaged.
- c. U.S. shippers are encouraged to either ship in ready-for-retail, properly labeled packaging, or in layer pack. Since repackaging of bulk packed products is extremely difficult without completely defrosting the product, layer packing may be a good alternative.
- d. This law impacts imports and domestic production equally.

Other aspects of the regulation relate to grading, classification, and microbiological testing of imported and domestically produced poultry. A translation of the regulation is available from AgBucharest by request.

IV. FOOD ADDITIVES REGULATIONS

The Public Health General Directorate and the State Sanitary Inspection within the Ministry of Health, together with The Department of Food Industry, Standards, Marks and Licenses within the Ministry of Agriculture are the authorities responsible for the regulating food additives and coloring additives for foodstuffs. The Order 438 of June 18, 2002 and the Order 295 of July 12, 2002, jointly issued by the two ministries, define additives permitted for use in foodstuffs. The National Authority for Consumer Protection - as a supervisory body - is also in charge of this issue.

In general, the relevant legislation parallels the UE regulatory framework in this field. Part of their national wide public awareness effort regarding food product safety, the National Authority for Consumer Protection and the Ministry of Health have recently launched an informative brochure containing a list of forbidden additives. The forbidden additives listed in this brochure are: E 116a, E 161 c-f, E 201, E 225, E 233, E 236, E 303, E 305, E 313, E 317, E 342, E 411, E 462, E 467, E 472 g, E 550, E 557, E 560, E 636, E 637, E 900 B as well as alpha and beta-ionone, fermented rice.

V. PESTICIDE AND OTHER CONTAMINANTS

Generally, Romania adopts the international standards (Codex Alimentarius) for tolerance for pesticides, herbicides and fungicides used against crop diseases and pests. The authority responsible for the registration of agricultural chemicals is the General Directorate for Environmental Protection within the Ministry of Agriculture.

US exporters can obtain a list of approved pesticides from:

The Ministry of Agriculture, Forests, Waters and Environment
General Directorate for Environmental Protection
12, Libertatii Blvd., sector 5
Bucharest, Romania
Phone: 40 21 4110298
Fax: 40 214110298

The major laws and regulations that provide regulatory framework for domestic and imported pesticides are:

GOR Emergency Ordinance 97/2001
Law 91 of March 18, 2003
Norm 157 of February 03, 2003

VI. OTHER REGULATIONS AND REQUIREMENTS

Romanian regulations require US companies exporting products of animal origin to Romania to be inspected by the US federal inspection service, respectively the Food Safety Inspection Service (FSIS).

The Romanian counterpart is the Veterinary and Food Safety Agency, which verifies whether import documentation complies with country's legislation. It also negotiates with the FSIS the type of certificate required for each product in accordance with the Romanian legislation.

Proper export documentation

Required documents for livestock products to be imported in Romania:

- Sanitary-veterinary approval.

- Health Certificate for meat intended for import to Romania (bilingual).
- Freezing Certificate issued by the producer, when applicable.
- Declaration of Conformity/Quality Certificate issued by the producer.
- Technical Description (especially for processed products).
- Certificate of origin (required by the Romanian Customs for calculating the applicable duty)

As an example, the bilingual (English and Romanian) health certificate (FSIS Form 9260-1) for poultry meat (the largest agricultural product shipped by the US to Romania) is summarized below.

Fresh poultry meat means any parts of domestic fowl, turkeys, guinea fowl, geese and ducks, which are fit for human consumption and which have not undergone any treatment other than cold treatment to ensure its preservation, and is vacuum wrapped meat or meat wrapped in a controlled atmosphere.

The following type of information should be provided by the USDA health certificate for poultry meat:

- name and address in full of company-importer;
- name and address in full of company-exporter;
- country of origin: the United States of America;
- region of origin;
- name of the products;
- number and type of packages;
- date of freezing;
- identification marks;
- export number of the establishment registered for exports (company, slaughterhouse, cutting plant, warehouse or refrigerated warehouse);
- countries of transit;
- means of transportation;
- certificate of fitness of the goods for the consumption;
- date and place of issuing of the document;
- name and self signed signature of the officially authorized state official issuing the document;
- original stamp of the state veterinary service.

The certificate of fitness of the goods for the consumption is a veterinary-sanitary statement by which the authorized person issuing the document officially declares the wholesomeness, safety and purpose of use of the product. By this, the official veterinarian certifies that:

1. That the United States or region is free from avian influenza and Newcastle disease, as defined in the International Animal Health Code of OIE.

2. That the meat described above is obtained from poultry which:

(a) have been held in the territory of the United States, the specified region, since hatching or have been imported as day-old chicks;

(b) came from holdings:

- which have not been placed under animal health restrictions in connection with a poultry disease;

- around which, within a radius of 10 km, there have been no outbreaks of avian influenza or Newcastle disease for at least 30 days;

(c) have not been slaughtered in the context of any animal health scheme for the control or eradication of poultry diseases;

- (d) have/have not been vaccinated against Newcastle disease using a live vaccine during the 30 days preceding slaughter;
- (e) during transport to the slaughterhouse did not come into contact with poultry suffering from avian influenza or Newcastle disease.

3. That the poultry meat described:

(a) comes from the slaughterhouses which, at the time of the slaughter, are not under restrictions due to a suspect or actual outbreak of avian influenza or Newcastle disease and around which, within a radius of 10 km, there have been no outbreaks of avian influenza or Newcastle disease for at least 30 days;

(b) has not been in contact, at any time of slaughter, cutting, storage or transport with meat which does not fulfill the requirements of Directive 91/494/EEC.

4. That the meat described fulfils the requirements of condition equivalent to Council Directive 71/118/EEC, and has been found fit for human consumption following ante and post-mortem inspection carried out in a manner equivalent to this Directive.

5. That the meat described above has/has not been subjected to an immersion chilling process.

6. That the meat described above has been marked in a manner equivalent to Article 2 of Decision 96/712/EEC.

Product samples shipped via express mail or parcel post are subject to the same import regulations.

VII. OTHER SPECIFIC STANDARDS

Organic Food

The Romanian market for organic food is at the very beginning. Even though the growth is estimated to double within the next couple years, the actual area of 44,000 HA (1% of the total arable area) is very low in comparison with other European countries. Except for ecological eggs and honey, the Romanian organic products are generally produced for exportation, due to both the reduced purchasing power of the population and the general low importance given to environmental and food issues. Production is limited mostly to grains, vegetables and forest fruits.

The Governmental Decision 34 of April 2000 sets out standards for production, classification, processing, packaging, importation, distribution, certification of the organic products and establishes the labeling procedure for such products. In 2003, the Romanian National Stamping Company revealed its intention to produce the secured "ecological" label, in an attempt to eliminate counterfeits.

In order to put into practice the existing regulations, the National Authority for Ecological Products was established within the Ministry of Agriculture. Imported products should be labeled as organic if they were produced by organic methods confirmed by the certificate of compliance. The label must contain: the name and the address of the producer/processor, the name of the product and the producing method, the name and the mark of the inspecting and certifying institution, the storage conditions, the minimum term of validity. The labels will also contain a special stamp for organic products registered at the State Office for Inventions and Patents (OSIM). It is forbidden to store ecological products and ordinary

products in the same place. The competent authority, which issues the ecological label, is the Ministry of Agriculture, Waters, Forests and Environment.

Organic products for trade should be stored separately from non-organic products. Storage and transportation of organic products is done in closed packaging and containers with the information on the name and address of manufacturer, name of certifying institutions, its ID number and certificate number.

Products derived from Biotechnology

Unique among the candidates to EU membership, Romania has pioneered the planting of biotech crops, especially soybeans. Currently, herbicide resistant soy is approved for commercialization, while several biotech corn and sugar beet products are approved for testing. In 2003, local farmers planted 70,000 hectares of a herbicide resistant variety soybeans, including 30,000 hectares of. These figures climbed in 2003 to 110,000 hectares and 60,000 hectares, respectively. However, the current GOR official position reflected in recently passed regulations favor the EU-line on biotech.

Legal Framework for Biotech in Romania

The GOR efforts to bring its regulatory capacity into line with EU rules and international agreements resulted in the passage of new legislation over the past two years. For genetically modified organisms (GMOs), Law 214 of April 19, 2002, effective from May 2002, enforces and amends GOR Ordinance 49/2000 on obtaining, testing, utilization, and commercialization of GMOs, as well as products derived from GMOs. The Law provides the main framework for bio-engineered products in Romania. Two other pieces of legislation relevant to biotech-related issues are: (1) GOR Decision 106/February 2002 on labeling food derived from GMOs or containing genetically modified additives or derived from GMOs and (2) Minister of Agriculture, Forests, Waters and Environment Order 462/2003, effective from July 2003, with provisions aimed at tracing biotech products.

According to Law 214/2002, the competent authorities in implementing and enforcing all activities related to the use of GMOs, respectively all activities concerning the deliberate release of GMOs are: (1) the Ministry for Waters and Environmental Protection, responsible for the issuance of authorizations/permits and carrying out the post-control of all related activities; (2) the Ministry of Agriculture and Food; (3) The Ministry of Health and Family; (4) the National Authority for Consumer Protection. As a result of the 2003 GOR reshuffle, the Ministry of Environment was absorbed by the Ministry of Agriculture and Food, which was renamed the Ministry of Agriculture, Forests, Waters and Environment per GOR Decision 739/2003.

The National Biosafety Commission (NBC), an independent scientific body, advises the executive authorities during the decision making process on biotech policy. The NBC consists of twelve scientists with a relevant background and who are members of the Romanian Academy or representatives of research institutes in life sciences, agriculture or medicine.

Law 214/2002 stipulates that, the user shall submit to the National Authority, prior to the utilization of any GMO, notification containing at least the information specified by Law 214. After receiving the notification, the NA will inform and consult with the public regarding the received notification and consult the Biosafety Commission, which will then evaluate the environmental and agricultural impact of such use. The NA will then also request specific assessments from the Ministry of Health and the National Authority for Consumer Protection (which is responsible for food and feed safety) on the impacts of such use on human health.

As the NA, the Ministry of Agriculture, Forests, Waters and Environment responds to the notifier within a period of 90 days after receipt of the notification whether the received notification is in compliance with the current legislation. The notifier may be required to submit additional information. If the proposed activity does not comply with the legislation in effect, the notification is rejected. The 90-day period referred does not include any periods of time during which the NA: (a) is awaiting further information requested from the notifier, (b) is awaiting the approval of the Biosafety Commission; (c) is conducting public hearings. If the National Authority considers that sufficient evidence has been gathered by releasing in the environment certain genetically modified organisms, it can decide to apply simplified approval procedures. The notifier may proceed with the proposed activity only after obtaining the NA authorization, and it must observe the conditions specified in the authorization. In-country field tests are required prior to granting the commercial status to biotech crops.

Contact Information

Notifications must be submitted to the General Directorate for Environmental Protection, headed by Dr. Ioan Jelev, tel. 40 1 410 0243, fax 40 1 335 5662. Dr. Jelev directly supervises the Department for Pollution Control and Bio-diversity Preservation, headed by Mrs. Adriana Baz, who is responsible for assessing the environmental impact of biotech products for which a notification is submitted. Likewise, agricultural aspects (i.e. is a particular bio-engineered crop a potential plant pest?) are dealt with by the General Directorate for Agricultural Policy Regulation and Implementation, headed by Mr. Vasile Bacila, tel. 40 1 315 9985, fax 40 1 313 2187. Dr. Klaus Fabritius from the Institute for Public Health of the Ministry of Health and Family, tel. 40 1 204 9209 and Mrs. Anica Popa, head of the Food Products Office of the National Authority for Consumer Protection, tel. 40 1 315 6692, are responsible for food and feed safety risk assessments in connection with GMOs.

Monitoring and Enforcement

According Law 214/2002, the NA officially issues the approval for releasing a specified genetically modified organism in the environment, while relevant departments respectively responsible for assessing different types of risk conduct post-approval surveillance to check compliance with authorization requirements.

Violations of Law 214/2002 provisions may become infringements according to the penal law and they are punished with a fine from ROL 10 million to 100 million (i.e. approximately \$300 to \$3000 at the current exchange rate) and/or temporary or final suspension of the activity, on a case by case basis. Specialized personnel authorized by the Ministry Agriculture, Waters, Forests and Environment, Ministry of Public Health and Family and the National Authority for Consumer Protection enforce the sanctions provided under Article (50) of the law. Law 214/2002 also states that if damage results from activities regulated through this law that is detrimental to human or animal health, to biological diversity or to the environment, the user is responsible for the damage. The nature and scope of the damage are to be established by a commission of experts appointed by the National Authority.

Traceability

Tracking biotech products in Romania has become stricter and more rigorous lately, from the regulatory perspective. Traceability is required as a consequence of the labeling requirements provided by Law 214/2002 and GOR Decision 106/2002, brought in line EU directives.

On July 29 the Minister of Agriculture, Waters, Forests and Environment issued its Order 462 which requires all farmers using seeds for biotech crops to report the area planted to

such seeds and the yields obtained. More specifically, all individuals/companies that cultivate biotech crops must submit two declarations to the Directorate for Agriculture and Rural Development of the Ministry of Agriculture, Waters, Forests and Environment, the first one within 10 days after sowing completed, while the second one within 10 days after harvest. The first declaration must describe the name of the crop, area cultivated with it, and the origin of the seed (whether acquired via procurement or own production). The second declaration must include the name of the plant, the production obtained and its destination (seed for sowing or consumption).

The new regulation on traceability requires companies involved in this business, when using or handling biotech products, to submit and keep information at each stage of placing them on the market. Companies are responsible for ensuring that a tracking system is in place.

Notification Dossier

The notification must include:

- a technical dossier providing specified information for carrying out the environmental risk assessment, especially: (i) general information on the notifier, including information on personnel and training; (ii) information regarding the genetically modified organism/organisms; (iii) information regarding the conditions of the release and the characteristics of the potential recipient environment; (iv) information regarding the impact of the genetically modified organism/organisms on the environment; (v) a monitoring plan, to identify the effects of the genetically modified organism/organisms on human health and environment; (vi) information on control and corrective methods, waste treatment and emergency response plans; (vii) a summary of the dossier.
- the environmental risk assessment study together with any bibliographic references and indications of the methods used;
- information regarding the results of the release of the same genetically modified organisms or of the same combinations of genetically modified organisms on the territory of Romania or elsewhere.

The notifier may refer to the data or the results from the notifications previously submitted by other notifiers, provided that the information, data and results are not confidential or the notifier has their consent. Simplified procedures may apply for GMOs already notified and/or approved in EU members and in OECD countries. In this situation, the notifier will present: (i) either a copy of the notification summary submitted by the national competent authorities in the member states to EU and OECD; (ii) or a copy of the EU and OECD documents which approve the release of the genetically modified organism on the territory of the member states.

Phytosanitary regulations

The import of live plants, fresh fruits, vegetables, grains, seeds and seeding materials, GM breeds as well as importation of samples for testing and experimentation or for market testing needs the approval of The Ministry of Agriculture, Waters, Forests and Environment. The MAWFE issues import approvals for seeds and seeding material valid for a maximum 6 month-period.

The phytosanitary legal framework is provided by the GOR Ordinance 136/2000, GOR Decision 1030/2001 and its accompanying Methodological Norm published on 10/18/2001. This Norm provides a full list of organisms considered pernicious on the Romanian territory and which are forbidden for importation. Also, agricultural products contaminated with the specified organisms are forbidden for importation.

Another annex to the Norm lists countries from which specified plants/agricultural products are banned for importation to Romania.

Very important is the Annex 5 to the Methodological Norm, specifying all plants and crop products which should be accompanied by a phytosanitary passport on the Romanian territory (Part A) or would require a phytosanitary certificate when imported to Romania.

This phytosanitary certificate, issued by APHIS, must accompany the products imported from the US, certifying that the product is free of quarantine organisms. The identification documents and quality documents (purity certificate and analysis bulletin) and the original labeling stamped on packages must also accompany the imported products.

Veterinary regulations

Imports of animals and products of animal origin are supervised by the Romanian Veterinary and Food Safety Agency, which closely cooperates with FAS Bucharest, FSIS and APHIS in Washington DC.

Live animals, meat, meat products, tripe and offals as well as bovine semen imported in Romania must be accompanied by a health certificate issued by a government-approved veterinary body. Importers must apply for an import license at the Veterinary and Food Safety Agency (VFSA).

The VFSA and FSIS are currently revisiting the health beef certificate for export to Romania, after an already reached agreement for eliminating the hormone-free requirement. This was needed after the BSE outbreak in Washington.

US exporters are advised to check with the Romanian importers about various standards that must be fulfilled regarding products which are to be sold on the Romanian market. The US exporters must also check with FSIS, the Romanian local authorities, FAS Bucharest or local importers in order to comply with the Romanian quality standards for storage conditions of meat and meat products and shelf life of the product (which depends on storage and temperature conditions provided by the Romanian legislation).

Before exporting semen or embryos to Romania, the US exporter should contact APHIS/VS at the following address:

National Center for Import and Export
Animals Program
Veterinary Service
Animal and Plant Health Inspection Service (APHIS)
US Department of Agriculture
4700 River Road Unit 39
Riverdale, MD 20737-1231
Phone: (301) 734-7511
Fax: (301) 734-6402

Marine Products

Seafood products to be exported to Romania require a special bilingual (English/Romanian) certificate, issued by the Seafood Inspection Program of the US Department of Commerce.

Contact information:
Seafood Inspection Program

1315 East-West Highway
Silver Spring, MD 20910
Tel. 301 713 2355
Fax 301 713 1081

The certificate is summarized below.

DETAILS IDENTIFYING THE FISHERY PRODUCTS

Species (scientific name)
State or type of processing: (refrigerated, frozen, dried, smoked, semi-cans, cans, etc)
Type of packaging
Number of packages
Net weight
Manufacturing date
Date of freezing
Temperature required during storage and transport
Identifying marks of packages

ORIGIN OF FISH AND FISHERY PRODUCTS

Address(es) and number(s) of preparation (s) or processing establishment(s) authorized for export by the competent authority

DESTINATION OF FISH OR FISHERY PRODUCTS

The fishery products are to be dispatched from: Place of dispatch
To: country and place of destination
By the following means of transport
Name and address of consignor
Name and address of consignee

HEALTH ATTESTATION

The official inspector should certify that:

the fish, crustaceans, gasteropodes, etc, are originated from hydrographic basins and fishing areas which are nor under veterinary restrictions and are unconditional fit for human consumption;

the fishery products described above have been handled, prepared or processed, identified, stored and transported under conditions at least equivalent to those laid down in Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products;

in addition, in the case of frozen or processed bivalve molluscs, the latter have been gathered in production areas subject to conditions at least equivalent to those laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs.

VIII. COPYRIGHT/ TRADEMARK LAWS

Intellectual property laws are in place in Romania. Each company is responsible for protecting its intellectual property rights. Although enforcement has been improving lately, the authorities still struggle to be more effective. Romania is signatory to a number of international Intellectual Property Rights conventions, including the Bern and Paris Conventions.

Patents

The Romanian Law protects the invention acts through patents. The applications, including a description of the invention, must be submitted in the Romanian language to the State Office for Inventions and Patents (OSIM). When written in another language, a translation into Romanian of the already submitted documentation must be provided within 2 months. Law 64 of October 1991 regulates the invention patents.

The State Office for Inventions and Patents can be found at: <http://www.osim.ro>

Copyrights

Romania enacted in March 1996 a new copyright law, which complies with international standards. It provides copyright protection during the author's life and another 70 years after his death, and protects authors, but also producers, artists and performers for both commercial and personal rights. The Romanian Office for Copyrights handles the issues related to copyrights.

US companies might find that enforcement of copyrights is still inadequate in Romania. The major problems are in the area of sound and video recordings as well as software. Law 202 of November 2000, regulates the involvement of customs bodies in copyright problem solving. The Romanian Office for Copyrights, the State Office for Inventions and Patents and the General Customs Department collaborate to solve the copyright infringements.

Detailed information concerning the General Customs Department can be found at: <http://www.customs.ro>

IX. IMPORT PROCEDURES

The possibility of establishing a business relationship as to imports/exports of animals, products and by-products of animal origin and fodder is regulated by the Ministerial Order 70 of August 11, 1998, issued by the Ministry of Agriculture, Waters, Forests and Environment.

This order approves the Sanitary-Veterinary Norm regarding the conditions and the procedure for sanitary veterinary notification of the import, export, and transit of animals, products and by-products of animal origin, fodder and other products, which might affect the public health and animals.

Veterinary and Food Safety Agency is responsible for enforcing all sanitary-veterinary legislation.

Importation and exportation of livestock and products require a sanitary-veterinary permit issued by the field office of the Veterinary and Food Safety Agency. In this case the following documents are necessary.

- a transit sanitary-vet certificate and an official document issued by the Veterinary and Food Safety Agency (pre-notification : the confirmation given by the Veterinary and

Food Safety Agency that to the the import can be made in specified sanitary-veterinary conditions);

- international sanitary certificate : issued by an official vet (FSIS) which confirms that the products of animal origin destined for the human consumption comply with the international norms enforced referring to veterinary hygiene of the products.
- international animal sanitation certificate issued by an official vet (FSIS) from the exporter country which confirms the health state of the animals and the vaccinations they have been administered.

In order to export/ import products, or by-products of animal origin any potential importer/ exporter must submit to the central or field office of the Veterinary and Food Safety Agency the following documents:

- a pro-forma invoice for the products to be exported into Romania;
- a copy of the certificate of registration, fiscal code, and the certificate of incorporation of the importing firm;
- a copy of the rental contract drawn up with the storage or processing company of the imported products;
- a copy of the sanitary -veterinary license to operate of the processing/importing company;
- -a technical description of the processed products issued by producers which must specify the composition , physical and chemical parameters as well as the microbiological parameters of the products.

APPENDIX. GOVERNMENTAL REGULATORY AGENCY CONTACTS

The Ministry of Agriculture, Forests, Waters and Environment
24, Bd. Carol I, sector 3,
Bucharest, Romania
Phone: 40 21 3072345
Fax: 40 21 3078635
Web site: <http://www.maap.ro>

The Romanian Veterinary and Food Safety Agency
1B Negustori St.
Bucharest, Romania
Phone: 40 21 3157875
Fax: 40 21 3124967

The General Directorate for Environmental Protection
12 Libertatii Blvd.
Bucharest, Romania
Phone: 40 214100215
Fax: 40 214100243
Web site: <http://www.mapm.ro>

The Ministry of Health
1-3, Cristian Popisteanu Str., sector 1
Bucharest, Romania
Phone: 40 213072500 or 40 213072600
Fax: 40 213136660
Web site: <http://www.ms.ro>

The National Authority for Consumer Protection

Address: 5 George Clemenceau St., Bucharest.
Phone: 40-21-312 12 75
Fax: 40 21 314 3462
Web site: www.anpc.ro
www.apc-romania.ro

For further information on this report, please contact the following office in Bucharest:

Foreign Agricultural Service Bucharest
American Embassy, Romania
7-9 Tudor Arghezi St.
Phone: 40 21 2100398
Fax: 40 21 2105998
E-mail: AgBucharest@usda.gov
Web site: <http://www.amembassy.ro>